UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

Civil Case No.: _____

EBONIA ELLIOTT-LEWIS
Individually and as Relator, and the
UNITED STATES OF AMERICA,

Plaintiffs/Relators

FILED UNDER SEAL
JURY TRIAL DEMANDED

vs.

ABBOTT LABORATORIES, INC.,

Defendant.

QUI TAM COMPLAINT

RELATOR, Ebonia Elliott-Lewis ("Elliott-Lewis"), brings this Qui Tam action in the name of the United States of America, by and through her undersigned attorney, David P. Angueira, and alleges as follows.

SUMMARY OF CLAIMS

These claims are brought by the relator Elliott-Lewis for violation of the False Claims Act, 31 U.S.C. § 3729 *et seq.,* Anti- Kickback Statute, *42 U.S.C. §1320a-7b;* Off Label Promotion 21 C.F.R 801.4 and Pre Approval Promotion 21 C.F.R 812.7

PARTIES

1. Relator, Elliott-Lewis is a citizen of the state of Massachusetts.

2. Defendant, Abbott Laboratories ("Abbott") is a duly organized corporation with a principle place of business at 100 Abbott Park Road, Abbott Park, Illinois. It maintains offices in Massachusetts. It routinely conducts business and accepts correspondence at its Massachusetts address.

3. Abbott may be served with process of this Court through its registered agent, CT Corporation System, 155 Federal Street, Suite 700, Boston, Massachusetts 02110.

JURISDICTION AND VENUE

4. This action arises under the False Claims Act, 31 U.S.C. § 3729 *et seq.*

5. This Court maintains subject matter jurisdiction over this action pursuant to 31 U.S.C. § 3732 (a) (False Claims Act) and 28 U.S.C. § 1331 (Federal Question).

6. Venue is proper in this Court pursuant to 31 U.S.C. § 3732 (a) because: (i) Abbott resides in this district; (ii) Abbott transacts business in this district and did so at all time relevant to this complaint; and, as averred below, (iii) Abbott committed acts proscribed by 28 U.S.C. § 3729 – acts giving rise to this action – within this district.

7. Elliott-Lewis served a copy of this complaint upon the United States, together with a written disclosure statement setting forth and enclosing all material evidence and information they possess, pursuant to the requirements of 31 U.S.C. § 3730 (b)(2).

8. Elliott-Lewis has complied with all other conditions precedent to bringing this action.

9. Elliott-Lewis is the original sources of, and has direct and independent knowledge of all allegations herein and has voluntarily provided such information to the Government.

1. EXECUTIVE SUMMARY

10. Elliott-Lewis is a 42-year-old African-American woman with substantial industry experience in the research, development, and commercialization of new medical devices. Elliott-Lewis was employed in the Medical Affairs department as a Medical Science Liaison[1] at Abbott Vascular (Santa Clara, CA), an Abbott Laboratories operating company. Her job title was "Regional Medical Science Manager, Northeast." She had an excellent job performance history; however, Abbott Vascular Medical Affair management has used her 2013 performance appraisal as one element in a campaign of retaliation by harassment.

11. She openly exercised her right to refuse participation in the illegal marketing and promotion of an investigational device (protected activity). As a result of her refusal, her supervisors retaliated against her by reducing her job responsibilities, hiring her replacement, excluding her from training and department activities, ignoring her requests for assistance with clinician-initiated requests, documenting unduly negative remarks about her job performance as part of her 2013 performance appraisal, suspending her pay, and terminating her employment (adverse actions). This campaign of retaliation was intended to induce her resignation or, by reducing her authority, create doubt about her capabilities, thereby positioning another candidate

to immediately assume her responsibilities (causal connection between the two).

12. On February 13, 2014, Elliott-Lewis filed a formal corporate compliance complaint with the Abbott Laboratories Office of Ethics and Compliance. Following direction from human resources, she filed a separate personnel complaint with Employee Relations (corporate human resources) on February 20, 2014.[2] After several delays in a poorly implemented company process, she was finally assigned a corporate investigator whom she met for the first time in an introductory conference call on March 6, 2014, three weeks after she initiated the original complaint. Months after her complaint was initiated, the internal investigation was still ongoing and she was terminated before the investigation was concluded.

INTRODUCTION

1.1. BACKGROUND

13. Abbott Vascular's evolving tolerance for noncompliance in the form of medical device off-label promotion (reference Code of Federal Regulations under 21CFR801.4)[3] and pre-approval promotion (reference Code of Federal Regulations under 21CFR812.7)[4] is largely driven by changing public perception and market dynamics. In December 2010, six (6) months after Elliott-Lewis was hired, Abbott Vascular was publicly embarrassed by these news articles:

> Mundy, Alicia and Burton, Thomas M. "Abbott Hired Barred Doctor." *Wall Street Journal.* Web. Updated December 6, 2010 12:01 a.m. ET.
>
> Hancock, Jay. "Threat betrays big medicine's profit obsession." *Baltimore Sun.* Web. December 06, 2010.

14. Abbott opened an internal investigation surrounding appropriateness of the company's relationship with Dr. Mark Midei.[5] As a result of these events, the company was in a state of hypervigilance with respect to compliance at the beginning of her tenure with the company. Shortly after Elliott-Lewis was hired, Colleen Baird and Charles "Chal" Berry (Sales Area Director) told her that in 2009, her predecessor Tom Maloney was terminated by her hiring manager Patricia Knipper for noncompliance. The Northeast Medical Science Manager position sat open for one year before she was hired. These facts contributed to a strained relationship between Medical Science and the Northeast region's commercial leadership long before Elliott-Lewis' arrival. Sometimes referred to internally as the "Fellows Factory," the Northeast is strategically important from a sales perspective because it is home to a high concentration of elite medical schools. Before receiving the offer for this job, Elliott-Lewis conducted three (3) telephone screenings and seven (7) face-to-face interviews, which required two separate visits to Santa Clara, CA, from her home in Boston, MA.

15. During the past several years, the following economic factors and market dynamics have contributed to declining profitability for Abbott Vascular's flagship product (XIENCE coronary stent):

1) Declining stent procedure volumes[6] in response to clinical trial findings[7] that stents provide no medical benefit over drugs in treating some heart disease; patients are also postponing elective stent procedures due to poor macroeconomic conditions.
2) Declining average sales price (ASP) due to an increase in the number of competitors.[8]
3) Rising cost of doing business due to the Affordable Care Act's tax on medical devices.

When Abbott Laboratories completed the AbbVie spin-off in 2013, Abbott Vascular immediately inherited more responsibility for the parent company's financial success since its performance became a greater percentage of the overall portfolio. Chief Medical Officer Chuck Simonton, in response to these market factors, has encouraged the Medical Science Managers to work closely with the sales team in a manner that is inappropriate for the role based on FDA guidance.

16. Also of note, the Department of Justice placed Abbott Laboratories under a Corporate Integrity Agreement (CIA) in 2012 for a multifaceted, off-label promotion scheme of the drug Depakote.[9] However, the recent corporate restructuring associated with the AbbVie spin-off allowed Abbott Laboratories to evade the CIA and transfer all liability to AbbVie:

"Following the separation, AbbVie will be subject to a Corporate Integrity Agreement entered into by Abbott on May 7, 2012 that requires enhancements to certain compliance procedures and contains reporting obligations including disclosure of financial payments to doctors. If AbbVie fails to comply with the CIA, the OIG may impose monetary penalties or exclude AbbVie from federal health care programs, including Medicare and Medicaid... The obligations of the CIA transfer to and become fully binding on AbbVie upon the separation and distribution." [10]

17. Elliott-Lewis was an Abbott Vascular Regional Medical Science Manager (synonymous with the industry term "medical science liaison") for the Northeast Region. Her geographic territory included the District of Columbia and the following states: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont, New Jersey, New York, Pennsylvania, Delaware, Virginia, Maryland, and West Virginia.

18. On 02/13/2014, Elliott-Lewis opened an internal compliance complaint accusing her managers (Baird, Sudhir, and Simonton) of retaliation by harassment because she refused to engage in:

a. off-label promotion based on unapproved indications for the XIENCE stent
b. pre-approval promotion of an investigational device containing the Bioresorbable Vascular Scaffold (BVS) technology

19. Elliott-Lewis also, on the direction of her local human resources manager Abby Trainor, opened a separate personnel ticket number on 02/20/2014 by calling an intake hotline. Elliott-Lewis told the intake associate that she had already opened a related compliance report, but when she read off the report number, the intake person refused to accept the information. He said, "We're not allowed to include compliance report numbers: that's our policy." Instead she submitted the personnel ticket number to the compliance email address as evidence.[11] Elliott-

Lewis' original complaint is about personnel actions ("retaliation and harassment") taken in response to her opposing an illegal activity (illegal marketing).[12] Abbott policies and reporting procedures are designed to separate documentation about this connection to protect the company from liability. On 02/20/2014 she received a standardized email response stating, "Thank you for calling the Office of Ethics and Compliance Helpline. The OEC will conduct a review of your concern and will take appropriate actions as needed." Dissatisfied with this response, Elliott-Lewis scheduled and flew to California for face-to-face meetings with Human Resources and Abbott Vascular Compliance Officer Jeff Berry. She discussed several concerns with Jeff but near the end of their meeting she realized he was not aware of her complaint details. She asked him whether he had reviewed her submissions to the Compliance Line. He responded, "Oh, those don't come to me. That goes to Chicago." Chicago, IL is home to Abbott Laboratories corporate headquarters. She was finally assigned a corporate investigator to address the compliance issues three (3) weeks after she opened the compliance report number.

1.2.COMPLAINTANT BIOGRAPHY[13]

20. Elliott-Lewis is a 42-year-old African-American woman with substantial industry experience in the research, development and commercialization of new devices. She has a Bachelor of Science degree in Electrical Engineering from Clemson University (Clemson, SC) and a Master of Science degree in Biomedical Engineering from Northwestern University (Evanston, IL). Before joining Abbott Laboratories, she worked for several large, multinational medical device manufacturers, including Johnson & Johnson, Siemens, and Covidien. She is a patent holder and has several peer-reviewed articles and abstracts.

21. Most of her career has been spent in the medical device industry; however, she started out in aerospace and defense as a radiofrequency circuit designer. She held top secret security clearances for seven years. She completed her undergraduate degree in Electrical Engineering on a full academic scholarship.

1.3. KEY PEOPLE

22. Abbott Vascular's Medical Science team consists of four (4) field positions and a project manager. Each field employee has the title "Regional Medical Science Manager" and a group of states comprise a geographic region and each region has an assigned field employee.[14]

- **Marinca Peters** - Medical Affairs project manager; reports to C. Baird
- **Patricia "Pat" Knipper** - resigned circa 2012 as Medical Science Director
- **Margaret (Quattrocchi) Campbell** - resigned April 2013 as National Medical Science Manager and Regional Medical Science Manager for the Southeast region
- **Roxanna Sharp** - resigned April 2013 as Regional Medical Science Manager for the MidAmerica region
- **Regina Deible** - hired in August 2013 as Regional Medical Science Manager for the Southeast region; reports to C. Baird
- **Felicia "Fely" Canorea Vega** - hired in December 2013 as Regional Medical Science Manager for the MidAmerica region; reports to C. Baird

- **Colleen Baird** - my immediate supervisor; she was promoted over me to National Medical Science Manager in April 2013 and she also acts as Regional Medical Science Manager for the Midwest region; reports to K. Sudhir
- **Krishnankutty "Krishna" Sudhir, MD, PhD** - Vice President of Medical Affairs and Product Performance; reports to C. Simonton
- **Charles "Chuck" Simonton, MD** - Chief Medical Officer at Abbott Vascular; senior executive who reports to the president of Abbott Vascular Chuck Foltz
- **James "Jim" Curcio** - Human Resources, Employee Relations Manager at Abbott Laboratories
- **Abby Trainor** - Human Resources, Senior Manager at Abbott Vascular
- **Jeff Berry** - Ethics & Compliance Officer at Abbott Vascular
- **Peter "Pete" Schutzel** - Internal Investigations Director at Abbott Laboratories

1.4. XIENCE Everolimus Eluting Coronary Stent System

23. The XIENCE V Stent is a metal scaffold with the drug everolimus contained in a thin coating. The XIENCE V Stent is mounted on a folded balloon attached to a catheter delivery system, for placement into the coronary artery (blood vessel supplying blood to the heart). The stent is made of a metal alloy and it comes in multiple sizes, in order to treat coronary arteries of different sizes. XIENCE is commercially available worldwide and has been consider the stent market leader for the past several years. Dual antiplatelet therapy (DAPT) after coronary stent implantation is associated with improved outcomes; however, sometimes DAPT must be stopped or interrupted (e.g. a patient who recently received a stent and now requires another surgery for hip replacement must have DAPT interrupted to control bleeding risks). This fact has led stent makers to tout their outcomes in patients who undergo "DAPT interruption."

1.5. BIORESORBABLE VASCULAR SCAFFOLD

24. Abbott's drug eluting, fully bioresorbable vascular scaffold (BVS) technology is important to the company's new product pipeline. Bioresorbable vascular scaffolds are made of polylactide, a naturally dissolvable material that is commonly used in medical implants such as dissolving suture anchors.

25. ABSORB BVS is an innovative device for the treatment of coronary artery disease, which is a narrowing of one or more arteries that supply blood to the heart. ABSORB works by opening a clogged vessel and restoring blood flow to the heart similar to a drug eluting metallic stent, the current standard of care. The device then dissolves into the blood vessel, leaving behind a treated vessel that may resume more natural function and movement because it is free of a permanent metallic implant.

26. Similarly, Abbott has a peripheral BVS device called ESPRIT. ESPRIT is based on a different mechanical design compared to ABSORB. Peripheral lesions are usually longer than coronary lesions. In addition, peripheral scaffolds must withstand greater mechanical

challenges (i.e. scaffolds must be more resistant to external compression).

27. With the AbbVie spin-off, medical devices became a larger percentage of the Abbott Laboratories business. Abbott's vascular products, including drug-eluting stents (DES) and bioresorbable vascular scaffold (BVS), generated $1.563 billion in worldwide 2013 revenue, including $510 million from domestic sales. [15] International sales comprise more than 60 percent of the total Vascular business and increased 5.3 percent operationally, driven by continued share gains of the XIENCE drug-eluting stent and ABSORB. ABSORB is commercially available in international markets where adoption appears to be growing despite the premium price (~2-3x the price of a traditional metal DES). [16] The typical pace of new technology adoption is extraordinarily rapid among interventional cardiologists. Studies show at least half of DES therapy use occurs in off-label scenarios. [17, 18]

2. CAUSE OF ACTION

28. Management exerted pressure on Elliott-Lewis to be proactive in reaching out to the clinical leaders in the Northeast region in an effort to influence those leaders to meet stent sales goals. Abbott Vascular Medical Affairs management encourages and rewards noncompliance in the form of medical device off-label promotion (in violation of Code of Federal Regulations under 21 CFR 801.4) and pre-approval promotion (in violation of Code of Federal Regulations under 21 CFR 812.7).

2.1. DISCRIMINATION

29. Elliott-Lewis is characterized by three (3) protected classes. Colleen Baird (age 53) and Regina Deible (age 50) are Caucasian women. Abbott Vascular Medical Affair management has used her performance 2013 appraisal as one element in a campaign of retaliation by harassment that has had an adverse effect on her career success, including these examples:

1. Abbott management reassigned her high-visibility projects to Colleen Baird, without explanation.

2. Abbott management recruited and hired a new employee (Regina Deible) that resides in Elliott-Lewis' geographic territory. Then, without her knowledge, they asked this new hire to cover assignments in Pittsburgh, Philadelphia, and New York City, which would normally fall within her purview.

3. Abbott management intentionally excluded and isolated her from key team activities, including training and team meetings held at Abbott Vascular headquarters in Santa Clara, CA, on February 17-18, 2014.

4. Abbott management used her 2013 performance review to document unduly negative remarks to induce her resignation and/or to bully her into engaging in off-label and pre-approval product promotion.

30. Both Regina and Colleen have a long-standing personal relationship with Dr. Simonton that extends beyond their time as Abbott employees. Elliott-Lewis has significant medical device industry experience and she holds a graduate degree in biomedical engineering. Baird and Deible have spent their careers in a hospital setting, not in industry, and they each have personal clinician relationship that they leverage to get physician face time, even without a bona fide scientific reason for making hospital visits. They each hold a Bachelor of Science in Nursing.

2.2. RETALIATION

31. Before and on May 9, 2013, Elliott-Lewis openly exercised her right to refuse participation in the illegal marketing and promotion of an investigational device (protected activity). As a result of her refusal, her supervisors retaliated against her by reducing her job responsibilities, hiring her replacement, excluding her from training and department activities, ignoring her requests for assistance with clinician-initiated requests, and documenting unduly negative remarks about her job performance as part of my 2013 performance appraisal (adverse actions). This campaign of retaliation was intended to induce her resignation by reducing her authority, creating doubt about her capabilities, and positioning another candidate to assume her responsibilities (causal connection between the two).

Opposition to illegal promotion

32. Sometime between late 2012 and early 2013, Margaret Campbell initiated discussions with the Office of Ethics and Compliance (Jason Bedell and Jeff Berry) for guidance on the appropriateness of the Medical Science delivering group presentations to hospitals about ABSORB. She told Elliott-Lewis' team that OEC was opposed to this activity for their team due to compliance concerns. On May 9, 2013, Colleen Baird, Marinca Peters, and Elliott-Lewis had a team meeting with Dr. Simonton where Colleen touted her leadership in developing a presentation about the "science behind ABSORB." Weeks before that meeting and also later that afternoon, Elliott-Lewis told Colleen that their Office of Ethics and Compliance (OEC) rejected the idea of their team presenting ABSORB material to groups. ABSORB is an investigational device that is in the pivotal trial phase in the United States. Colleen developed the presentation materials and presented them to a hospital group. Dr. Simonton was especially supportive of this activity. Several of Elliott-Lewis' high profile projects were reassigned to Colleen throughout 2013.

New employee hired to replace Elliott-Lewis ahead of her departure

33. In mid-August 2013, Regina Deible was hired as Regional Medical Science Manager of the Southeast Region. Regina lives in the Washington, DC metro area, within the Northeast territory boundary and Elliott-Lewis learned in January 2014 that Chuck Simonton was assigning her work to Regina.

Management initiated documentation campaign to damage her career

34. On February 12, 2014, Colleen Baird met Elliott-Lewis in New Haven, CT for a field ride and her scheduled performance review; however she postponed the review, saying she had to rewrite it based on feedback from Chuck Simonton and Krishna Sudhir.[19] On that day, Elliott-Lewis realized that Chuck, Krishna and Colleen were either trying to compel her to comply with the illegal marketing plans or they were trying to damage her credibility and create a justification to remove her so that Regina Deible could assume her role. On February 13, 2014, Elliott-Lewis filed a corporate compliance complaint and was issued Report number 1402ABT10003. Following direction by human resources, on February 20, 2014, Elliott-Lewis filed a separate personnel complaint with Employee Relations (corporate human resources) and was issued ticket number 8000765131.

Management excluded Elliott-Lewis from key training and team meetings

35. On February 17-18, 2014, Colleen Baird scheduled a team meeting and Mitraclip training in Santa Clara, CA, and Elliott-Lewis was the only Medical Science team member who was not invited.

Management ignored Elliott-Lewis when she asked for help with an unsolicited physician request [20, 21, 22]

See email exchange about Dr. Savage's investigator sponsored study (ISS).

Management documented unduly negative remarks about Elliott-Lewis job performance

36. On February 27, 2014, Colleen Baird emailed Elliott-Lewis her 2013 performance feedback[23], which was unduly negative in tone [24] and out of character [25, 26]. Elliott-Lewis told her that the remarks were not consistent with prior feedback she had received from her, Krishna[27], or Chuck[28]. They began to discuss the review by phone that day, but she abruptly ended the call after 8 minutes (based on her iPhone call log) and she requested that they meet with Human Resources present when Elliott-Lewis asked why the development feedback had never been communicated to her before. Colleen rescheduled the performance review a third time for 2/28 and then canceled that meeting as well based on advice from Human Resources Senior Manager Abby Trainor.

37. After several delays in a poorly implemented company process, Elliott-Lewis was finally assigned a corporate investigator whom she met for the first time in an introductory conference call on March 6, 2014, three weeks after she initiated the complaint. Elliott-Lewis composed a performance appraisal rebuttal.[29] Jim Curcio suggested that he and Elliott-Lewis have a call with Colleen. Colleen asked Jim to invite Krishna to the call. Jim led a conference call with Krishna, Colleen and Elliott-Lewis on March 19, 2014.[30]

2.3.FALSE CLAIMS ACT AND ANTI-KICKBACK STATUTE VIOLATIONS

ABSORB AND ESPRIT

38. Abbott expects the ABSORB device to supplant the current generation of metal drug-eluting stent technology and the commercial success of this product is important to Abbott Vascular and Abbott Laboratories as illustrated by the following 2014 performance goal, sent to Elliott-Lewis by Colleen Baird and Krishna Sudhir: "Increase ABSORB's penetration into PCI market."[31] Elliott-Lewis' Medical Science team only worked with domestic physicians and ABSORB is not approved in the United States, so a performance metric like this[32] is highly inappropriate for a person in her role.

39. *Abbott Vascular Medical Science Manager Acceptable Practices Policy* described acceptable practices for Elliott-Lewis' job title as an Abbott Vascular Medical Science Manager ("MSM"). Both her immediate supervisor (Colleen Baird) and the new employee that she believed was hired to replace her (Regina Deible) have violated this policy by proactively giving inappropriate promotional presentations about an investigational device called the ABSORB Bioresorbable Vascular Scaffold.[33]

"AV employees must not interfere with the independent nature of accredited medical education activities. Accordingly, MSMs may not speak at Continuing Medical Education programs supported through an educational grant by AV. In addition, MSMs may not distribute enduring materials to attendees, nor provide input on the activity content, faculty selection, or faculty presentations (including preparation of slides or slide decks for speaker presentations).

Except as otherwise noted in this policy, MSMs may not proactively engage HCP/Customers in discussions about Off-label use of AV product or in discussions about competitor products, and may provide Off-label information only in response to an Unsolicited Request for information from the HCP/Customer." [34]

40. Abbott routinely gives a large educational grant[35] to the Vascular Interventional Advances (VIVA) conference. For a Medical Science Manager to give a proactive, group presentation about an investigational device like the ABSORB Bioresorbable Scaffold at this conference violates the policy for Elliott-Lewis' role. Regina Deible was hired as an Abbott Vascular Medical Science Manager in August 2013. Her presentation about the investigational device ABSORB was given on October 6, 2013.[36]

41. Abbott policy prohibits a medical science manager from influencing continuing medical education (CME) content. Abbott violated its own policy by allowing Deible to give a presentation at an Abbott-funded CME event. The conflict of interest (a company employee giving a presentation about the company's investigational device at a company-funded "independent" CME event) violates standards set forth by the Accreditation Council for Continuing Medical Education (ACCME)[37] including:

1. Independence
2. Resolution of Personal Conflicts of Interest
3. Appropriate Use of Commercial Support
4. Appropriate Management of Associated Commercial Promotion
5. Content and Format without Commercial Bias
6. Disclosures Relevant to Potential Commercial Bias

42. The company required Deible to "route her slides" for review by internal stakeholders (e.g. legal-regulatory, company Office of Ethics and Compliance) and that review process is evidence that the MSM Acceptable Practices policy violation occurred with company support. Deible's presentation title was "Bioresorbable Vascular Scaffolds: The Next Greatest Thing?" Abbott is currently in a US pivotal trial for an investigational device called the ABSORB Bioresorbable Vascular Scaffold System. Regina circumvented the conference disclosure policy by listing her affiliation as "Johns Hopkins"[38, 39] and, by describing herself this way, she withheld information about her industry affiliation from the audience. Her presentation materials were also distributed to all conference attendees through the VIVA website.

43. In addition, the slides Deible used contain superiority claims about an investigational device that is not FDA approved based on an indication that is not part of the pivotal trial study plan. Her slides show "best long-term outcomes" using the Bioresorbable Vascular Scaffold in superficial femoral artery (SFA) revascularization, which is a peripheral artery disease application that is not part of the FDA pivotal study. The SFA application is being investigated under the international ESPRIT I Clinical Investigation (http://clinicaltrials.gov/show/NCT01468974). Abbott's FDA pivotal trial is about treating coronary artery disease (heart disease), not peripheral artery disease (vessel disease in the groin/legs).

44. Statements the company makes now about an upcoming product approval create an impression for clinicians who may ultimately influence that product's purchase. Before FDA approval, if a device maker describes uses that are not ultimately approved, that medical device company is creating an off-label promotion scenario that will inappropriately influence the healthcare marketplace when the legal commercial product introduction finally occurs. Also of note, Abbott received an FDA warning letter in December 2007 for illegally promoting the Absolute biliary stent at the same VIVA conference event in September 2007.

XIENCE

45. In addition to supporting pre-approval promotion of the investigational device ABSORB, Abbott encourages and supports off-label promotion of the XIENCE stents in various ways. In response to DAPT interruption claims made by Medtronic [40, 41], Abbott re-focused marketing efforts around this and other off-label topics. [42, 43, 44, 45, 46, 47, 48]

46. Abbott uses communication tools like the Chief Medical Officer's (CMO) US Newsletter to proactively disseminate off-label clinical data (see newsletter attachment which was disseminated to ~2500 physicians). These newsletters are developed with marketing messages that are distributed in conjunction with major conference events. Abbott justifies this promotional activity by proactively disseminating the material to physicians who have a contractual agreement or other business relationship with the company. Newsletter recipients include clinical trial investigators, speaker's bureau participants, and physician consultants: this group reflects a significant portion of the United States key opinion leaders, many of whom have academic appointments at medical schools. A disproportionate number of these key opinion leaders are located in the Northeast (i.e. New England and Mid-Atlantic states). This ongoing

practice of proactive dissemination is used to circumvent the FDA requirement that off-label information may only be disseminated in response to a narrowly-tailored, unsolicited request. Brand XIENCE is commercially available in the USA and it is mislabeled, in violation of 21 U.S.C. 360e of the FD&C Act, 21 CFR 801.4 and/or all other applicable federal regulations based on the off-label newsletter dissemination.

3. CORPORATE MOTIVATION

47. Abbott willingness to incur the risk associated with illegal promotion can be explained by three potential threats that could compromise the BVS technology's commercial success: competition, limited clinical applicability, inability to achieve economies of scale.

3.1.COMPETITION

48. Abbott's ABSORB could be the first commercially available BVS device in the United States with Elixir Medical Corporation being the only close competitor. This fact makes Elixir an attractive acquisition target for one of Abbott's large competitors, such as Medtronic or Boston Scientific. Elixir might even provide a market re-entry opportunity for Johnson & Johnson CORDIS, which exited the lucrative stent market in 2011.

49. The small number of scaffold manufacturers is especially troublesome for all health care payers because competitive bidding programs are ineffective at managing costs. Abbott is working diligently to create a new Medicare payment category for scaffolds. Reassignment to a higher paying category may occur if certain cases are considered to be systematically more costly because of new technology use. This scenario is similar to what happened in 2003 when the Centers for Medicare & Medicaid Services (CMS) established higher payment rates for angioplasty involving the use of coronary drug-eluting stents (DES). As mentioned previously, the overall market for coronary stenting is shrinking, but these companies use their influence with physicians to drive new technology adoption. Maintaining (and growing) market share today is critical to future commercial success; consequently, Abbott's risk appetite for illegal marketing has expanded.

3.2.LIMITED CLINICAL APPLICABILITY

50. Abbott's revenue would be adversely impacted if the profitable BVS technology is not an appropriate replacement for metal drug-eluting stents in a significant number of cases. Findings already indicate that BVS technology may not perform as well in heavily calcified lesions. In addition, recently announced results suggest that the scaffold thrombosis rate is not negligible and may exceed the thrombosis rates for similar devices. Thrombosis is associated with heart attack or death. Study findings also suggest that clinical outcomes suffer as more complex patients are treated using the scaffold (SOURCE: Capodanno D, Gori T, Nef H, et al. Percutaneous coronary intervention with everolimus-eluting bioresorbable vascular scaffolds in routine clinical practice: early and midterm outcomes from the European multicenter GHOST-EU registry. EuroIntervention. 2014;Epub ahead of print). These factors may limit commercial

penetration for the BVS device.

3.3.INABILITY TO ACHIEVE ECONOMIES OF SCALE

51. BVS technology varies significantly compared to metal drug-eluting stents with respect to raw materials, manufacturing processes, and even storage requirements. These differences create manufacturing set-up costs. Abbott will realize a cost advantage as it increases the number of BVS devices it produces since the company has the same initial set-up cost regardless of the number of scaffolds produced. Once these costs are covered, there is a marginal extra cost for each additional scaffold. This concept is called "economies of scale."

52. Abbott's objective is to secure as much metal stent market share as possible in the United States ahead of the ABSORB BVS launch with the goal of supplanting those metal stent accounts with BVS technology. Abbott had early indications of higher thrombosis rates and poor performance in calcified lesions for BVS technology by 2013. In order to offset those lost opportunities, Abbott began discussions with physicians about emerging clinical applications, including suggesting that BVS technology can:

- Be used to "pave plaques" with a high likelihood of rupture, thereby preventing a heart attack (acute myocardial infarction or AMI)
- Control or reduce instances of angina and ischemia associated with percutaneous coronary intervention (PCI)

53. Prohibited marketing tactics help the company by hedging downside financial risk. CMS Medicare Administrative Contractors effectively "underwrite" the BVS technology by reimbursing scaffolds that are used in the ABSORB III pivotal trial under an investigational device exemption (IDE). Clinical studies, like ABSORB III, in support of a PMA are subject to the investigational device exemption (IDE) regulations (see Sec. 812.7 Prohibition of promotion and other practices: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812&showFR=1&subpartNode=21:8.0.1.1.9.1):

> "A sponsor, investigator, or any person acting for or on behalf of a sponsor or investigator shall not:
>
> (a) Promote or test market an investigational device, until after FDA has approved the device for commercial distribution...
>
> (d) Represent that an investigational device is safe or effective for the purposes for which it is being investigated."

Abbott's presentation of the BVS technology in a peripheral vascular disease forum for continuing medical education (CME) helps to gain the confidence of new clinician users in an effort to influence referrals and drive scaffold revenue. In contrast to the coronary procedure decline, peripheral vascular cases are on the rise because of its disproportionate effect on the

rapidly-growing US aging population. At the conference, Abbott told clinicians that investigational BVS technology delivers superior long-term peripheral outcomes compared to the standard of care: making this statement without regulatory approval in a CME forum, is a form of illegal marketing and promotion that is obviously financially beneficial to the company. A Class III device (e.g. ABSORB and ESPRIT) that fails to meet PMA requirements is considered to be adulterated under section 501(f) of the FD&C Act (see also section 351(f) and 351(i) of the FD&C Act) and cannot be marketed. Brand ABSORB is an investigational device currently in a US pivotal study called "ABSORB III". Both ABSORB and ESPRIT products are adulterated by the events described. In addition to tainting Medicare claims for ABSORB and ESPRIT branded scaffolds, these illegal acts render Medicare claims false for any bioresorbable scaffold-based product for which Abbott receives revenue, now and in the future.

ESTIMATING DAMAGES

3.4.*Coronary Artery Disease*

54. Abbott is marketing the ABSORB scaffold in the United States even though the device has not received FDA approval. The bioresorbable vascular scaffold is sometimes referred to as the "fourth generation" stent and it is likely to replace metal drug eluting stents (DES) in the same way DES devices replaced bare metal stents (BMS) and BMS devices replaced angioplasty. These advancements carry a pricing premium and, based on the commercial success of ABSORB in international markets, a premium of double to triple the DES pricing has not deterred the product's adoption. In 2013, Abbott's metal stent revenue was more than $500 million domestically. Upon FDA approval (expected in 2016), if ABSORB becomes the treatment of choice in half of these instances, domestic ABSORB revenue could balloon to $500 to 750 Million annually:

($250M*ABSORB LOW price premium) = ($250M*2) = $ 500 Million

($250M*ABSORB HIGH price premium) = ($250M*3) = $ 750 Million

55. The over-utilization opportunity lies in the fact that Abbott is promoting the device ahead FDA approval. Abbott is also already marketing BVS for clinical uses that are not yet under consideration by FDA, such as peripheral vascular disease. Based on a peer-reviewed 2010 publication called *Insurance type influences the use of drug-eluting stents* (Gaglia et al 2010), 45.2% of percutaneous coronary intervention (PCI) with stenting patients had Medicare while 3.7% had Medicaid. Consequently, approximately half of patients who undergo PCI with stenting have either Medicare or Medicaid.

56. Note that because the false claim is based on pre-approval promotion, every resulting post-approval BVS Medicare or Medicaid payment will be subject to penalties. Upon FDA approval, if Abbott successfully uses false claims and product seeding tactics to supplant half of its own metal stent sales with BVS device sales, the US government will pay at least $250 Million annually as a consequence. Today Abbott has 60-70% stent market share; however, if these schemes also help the company steal stent market share from competitors like Boston Scientific and Medtronic, the government will incur even greater financial damages.

3.5. *Peripheral Artery Disease*

57. Abbott plans to improve profits by expanding BVS use into clinical applications with expected procedure volume growth, including peripheral artery disease (PAD). In 2013 Abbott acquired IDEV Technologies and then in March 2014, Abbott announced FDA approval of its SUPERA® Stent to treat people with PAD. SUPERA gives Abbott an "on-label" reason to build business with doctors who will one day implant its lucrative scaffold technology. Peripheral artery disease of the lower extremities has become increasingly recognized as a major contributor to the cardiovascular public health burden. Lower-extremity PAD is estimated to affect 12% to 15% of patients over age 65 years and between 8 and 10 million people in the United States, with the expectation that the prevalence will increase significantly as the population ages, becomes more obese, and as diabetes becomes more common.

58. According to the article *National health care costs of peripheral arterial disease in the Medicare population* (Hirsch et al 2008), 6.8% of the elderly Medicare population received treatment for PAD. Treatment increased with age at rates of 4.5%, 7.5%, and 11.8% for individuals aged 65–74, 75–84, and >85 years, respectively. PAD-related costs accounted for approximately 13% of all Medicare Part A and B expenditures for the PAD-treated patients, and 2.3% of total Medicare Part A and B expenditures. The cost of PAD-related care in the Medicare population is substantial and there is a known temporal trend toward increasing use of endovascular procedures for revascularization of the lower limbs.

59. Abbott's shrinking coronary stent profitability would be mitigated by migrating patients from metal stents to the more profitable BVS device. In a press release (ABBOTT INITIATES CLINICAL TRIAL TO STUDY DRUG ELUTING BIORESORBABLE THERAPY FOR TREATMENT OF PERIPHERAL ARTERY DISEASE Thursday 22nd December, 2011), Dr. Simonton is quoted: "We've seen promising long-term clinical data with our bioresorbable therapy in coronary patients, and we believe there is potential for this technology in the treatment of PAD." The peer-reviewed article *National trends in lower extremity bypass surgery, endovascular interventions, and major amputations* (Goodney et al 2009) summarizes endovascular procedures per 100,000 Medicare patients in 2006 as 91,184, 62 procedures for Iliac, Femoral-popliteal, Tibial cases respectively. There are 50.3 million Medicare-Part A beneficiaries. If one BVS-related false claim per patient is attributed to only 6 percent of lower extremity, endovascular intervention angioplasty patients, the result is more than 10,000 claims that are subject to federal penalties:

((91+184+62)/100,000)*50,300,000*0.06 = 10,170 false claims

60. These 10,000 peripheral vascular false claims are in addition to the $250 million in Medicare payments incurred due to coronary false claims. Cardiologists and vascular surgeons have become the specialists most commonly providing peripheral vascular interventions (in the past these procedures were performed by radiologists). Interventional cardiologists represent Abbott Vascular's core customer base. These facts make Abbott's promotion of the investigational BVS scaffold at the large vascular intervention conference especially egregious and the company's plans to promote a financially favorable clinical use are clear, despite the lack of adequate supporting clinical evidence or mandatory regulatory approval.

4. CHRONOLOGY OF EVENTS

61. **July 2012**
Expense audit

August 23, 2012 [49]
Management assigns Elliott-Lewis to lead ABSORB/ABSORB III

December 2012
ABSORB III investigator meeting

February 2013
ABSORB III Medicare meeting assigned to C Baird without explanation

Around First Quarter 2013
Margaret Campbell initiated OEC meetings to discuss giving group presentations to clinicians about ABSORB

April 2013
Sharp, Campbell resign

April 2013
Baird promoted to National Manager

Early May 2013
SCAI meeting with Baird, Simonton, Peters

Mid-year 2013
Colleen Baird informs Elliott-Lewis that she delivered group presentation to (Ohio? - Cleveland Clinic?) clinicians about ABSORB and that she was reprimanded internally for doing so

Mid-year 2013
Colleen Baird illness

August 2013
Regina Deible hired

August 2013
Midyear review - CB/EEL salary disparity revelation

September 2013

Abbott supports Deible as VIVA CME faculty by reviewing and approving her slide presentation (even though MSM giving a talk at Abbott funded CME event violates company policy)

October 2013
Deible attends VIVA CME event registered under "Johns Hopkins," hiding her affiliation with Abbott

Thanksgiving 2013
Colleen Baird illness

December 5, 2013 [50]
MSM Q4 Meeting with Pacitti - Chuck S quote on the way to lunch: "You should be able to do your job without wondering whether you're gonna get fired." Elliott-Lewis' reply, "I'm glad you said it."

January 2014
Medical affairs management initiates MSM policy edits to relax compliance requirements

January 21, 2014 [51, 52]
Informed of R. Deible's Pennsylvania assignments

February 12, 2014
Field ride with Baird - performance review postponed, CB rejects Elliott-Lewis' request to join the upcoming layoff

February 13, 2014
Initiated internal OEC complaint via hotline/intake citing Simonton, Sudhir, and Baird for retaliation and harassment (Report number 1402ABT10003)

February 13, 2014 [53]
Regina Deible contacted Elliott-Lewis at 10:19 am to tell her that she will be delivering a clinical education presentation at North Shore University Hospital in New York. She told her that she would be doing the talk as a favor to a physician assistant friend and that the site is also up for contract renewal with Abbott. She said she didn't want Elliott-Lewis to be blindsided when she made this disclosure during the Medical Science call with Sales Area Director Chal Berry at 11 am. Colleen Baird initiated this recurring conference call for them to provide a commercial leader with high-level updates on their activities in key regional accounts. Regina did not describe any activities in the Southeast: this upcoming New York event was the only event she highlighted.

February 17-21, 2014
Vacation

February 17-18, 2014
Medical Science team Mitaclip training and team meeting

February 17, 2014
Abbott reduction-in-force; hundreds of layoffs announced at internal staff meeting

February 20, 2014
Elliott-Lewis initiated internal HR/Employee Relations complaint via hotline/intake; hotline refused to accept my OEC Report number 1402ABT10003 on the HR ticket; issued HR ticket number 8000765131

February 20, 2014 C. Baird Vacation

February 20, 2014 [54, 55]
Form email response received from OEC: "The OEC will conduct a review of your concern and will take appropriate actions as needed." No investigator assigned according to Jim Curcio.

February 24, 2014
Initiated trip to CA for face-to-face meetings with Abbott Vascular HR and OEC when no investigator contacted Elliott-Lewis about her complaint under Report number 1402ABT10003

February 25, 2014
Chuck and Krishna ignored Elliott-Lewis' request for help with PA physician Dr. Savage

February 27, 2014
Performance appraisal received in writing; performance review call started and ended within 8 minutes— then postponed twice

March 6, 2014
First meeting with corporate OEC investigator (3 weeks after my complaint was initiated)

March 12-14, 17, 18, 2014
Sick leave

March 13, 2014
First mental health appointment through Ceridian (Employee assistance program)
Primary Care appointment

March 19, 2014
Rebuttal meeting with Jim Curcio, Colleen— Colleen asks to include Krishna at last minute

March 19, 2014 [56]
Rebuttal meeting notes (see email exchange with Jim Curcio)
JIM: She thinks that you have been marginalizing her.

KRISHNA: "I don't understand why you are so resistant to constructive feedback. We like you. We are trying to help you. There have been many times in my career when I have received seemingly negative comments that have helped me to improve."

ME: *"To clarify, I asked for HR assistance on 2/13, the day after I my field ride with Colleen. I tried summarize my conversation with her that day in the message I sent, but I would encourage you to talk to her about our discussion that day. When I asked HR to intervene, I didn't even know what you wrote <in the review>. I am your subordinate and you, as my superior, have chosen to deliver negative feedback to me for the very first time using a format that is permanently documented."*

{long silence}

(discussion ensues about timing of feedback and various delays in delivery of the review, then Krishna asks that we stop "focusing on process" and discuss content)

ME: I am the only MSM who is continually losing leadership opportunities. My work keeps getting reassigned to my peers. Please elaborate on your comment here*: "Eboni needs to focus on building her relationships internally and externally to more effectively impact the Northeast region."*

KRISHNA: The Northeast is very dynamic and strategically important. There are a lot of important KOLs there. *"If I were you, I would be glad to be receiving the extra assistance."*

ME: I understand that you might see this as helpful but I do not think it is helpful. "*You are not allowing me to execute on the projects that I cultivated, then you say I am not making an impact in the territory.*" You are making assignment changes and decisions without even talking to me.

KRISHNA: "*We're busy and we can't be expected to discuss with you every little assignment change. Cut management some slack.*" The team is very small. "*We don't look at who's qualified, we look at who's available.*" [57] I could argue that Roxanna with her clinical experience was more qualified than you to lead the TRA project.

ME: "*That TRA project was not assigned to me: I volunteered. That is my point to you. My point to you is that assignments are not coming to me. I am simply asking for equity and parity in the way assignments are made."*

KRISHNA: *"You are suggesting that we treat you differently." "You are using words like 'usurp' which really shows a lot -- people become too territorial."* Chuck has gone all over the country, I do the same and Priya has gone to Midamerica and other regions as well. We go where the need is and the Northeast is a very important region.

ME: *"Those examples you offered, none of those people are MSMs. They are not my peers. Can you offer even ONE example of a MSM who has had a leadership role taken away and then reassigned to another MSM in a different geography?"*

{long silence}

ME: I can say I have had my work taken away, but I have NEVER been the recipient of one of these reassignments. *"If you keep reassigning my activities to my peers, you muddy the waters in accurately assessing my impact in the territory and you can't rank me against them fairly. I agree that the Northeast region is busy and very large but a more efficient way to address the issue is to do what I've suggested in the past: redraw the territory lines to accurately reflect the distribution of labor."*

February-March 2014 [58]
Individual 2014 goals and objectives do not comply with FDA guidance including, "Increase ABSORB's penetration into PCI market"

March 20-21, 2014
Vacation days requested for medical appointments with mental health specialist and primary care physician???

March 20, 2014
Psych appt; first day unable to work as documented by primary care physician

March 21, 2014 [59]
Primary Care appt; Elliott-Lewis made intake call to MATRIX for leave request Medical Leave requested for stress due to workplace harassment and retaliation (included reference to OEC report number and HR ticket number in request)

April 1, 2014 [60]
Elliott-Lewis sent email request for investigation status to Pete (corporate OEC - internal director); no response received

April 10, 2014
Short term medical leave (STML) request denied effective 03/24/2014

Early April 2014

Pay suspended

April 28, 2014 [61, 62]
Elliott-Lewis' first written request to be placed on paid leave

March 28 - May 1, 2014
Family Leave on Absence (FLOA) approved for 03/24/14 through 05/01/14

May 2, 2014
Elliott-Lewis' second written request to be placed on paid leave

May 3, 2014
Elliott-Lewis submitted a fraud report to OIG Hotline Operations at http://oig.hhs.gov/fraud/hotline

May 8, 2014
Primary care appointment with follow up appointment scheduled for July 2014
Pay expected for pay period ending May 11 was not received

May 9, 2014 [63]
Termination notice received from Jim Curcio -- despite her written request to be placed on paid leave Elliott-Lewis was terminated with accrued, yet unused vacation hours.

COUNT I
United States of America and Relator, Ebonia Elliott-Lewis, Against Abbott for Violations of 31 U.S.C. §3729
False Claims Act

62. The Relator, Elliott-Lewis, repeats and restates the allegations contained in paragraphs 1 through 61 and incorporate said allegations herein by reference.

63. Pursuant to 31 U.S.C. §3729, any person who

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent;

(C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);

(D) has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property;

(E) is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(F) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge property; or

(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government, is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains because of the act of that person.

(2) REDUCED DAMAGES.—If the court finds that—

(A) the person committing the violation of this subsection furnished officials of the United States responsible for investigating false claims violations with all information known to such person about the violation within 30 days after the date on which the defendant first obtained the information;

(B) such person fully cooperated with any Government investigation of such violation; and

(C) at the time such person furnished the United States with the information about the violation, no criminal prosecution, civil action, or administrative action had commenced under this title with respect to such violation, and the person did not have actual knowledge of the existence of an investigation into such violation, the court may assess not less than 2 times the amount of damages which the Government sustains because of the act of that person.

(3) COSTS OF CIVIL ACTIONS.—A person violating this subsection shall also be liable to the United States Government for the costs of a civil action brought to recover any such penalty or damages.

64. The Defendant has violated §3729 on multiple occasions by providing false and misleading information to the United States government. Specifically, the Defendant knowingly presented or caused to be presented false or fraudulent claims for payments or approvals including, but not limited to violation of False Claim Act regulations, anti-kickback regulations, marking false therapeutic claims, and unlawful promotion during the pre and post-approval process. These violations include violations of 21 C.F.R 801.4 and 21 C.F.R 812.7

65. The Defendant knowingly made, used or caused to be made or used false records or statements material to a false or fraudulent claim.

66. The Defendant conspired to commit and did commit violations of subparagraph (A), (B), (C), (E) and/or (G).

67. More specifically the Defendant engaged in conduct which was deceitful and intentionally misleading by failing to have policies and procedures in place to ensure all applicable government regulations and requirements were met including, but not limited to, proper anti kick-back policies implemented and enforced in violation of §3729 and the Anti Kick-back Statute, off-label marketing and pre and post approval marketing.

WHEREFORE, the Relator, Elliott-Lewis demands judgment against the defendant, in an amount that this Honorable Court shall deem just and proper, together with attorneys fees, costs, interest and punitive damages.

COUNT II

United States of American and Relator, Ebonia Elliott-Lewis, Against Abbott for Violations of 42 U.S.C. § 1320a–7b Anti-Kickback Statute

68. The Relator, Elliott-Lewis, repeats and restates the allegations contained in paragraphs 1 through 67 and incorporate said allegations herein by reference.

69. Abbott has engaged in conduct which violates Sunshine Laws and 42 U.S.C. §1320a-7b (Anti Kick-back Statute) by engaging in conduct that improperly seeks special arrangements between Abbott and medical providers in exchange for special or preferential treatment in violation of federal law.

WHEREFORE, the Relator, Elliott-Lewis demands judgment against the defendant, in an amount that this Honorable Court shall deem just and proper, together with attorneys fees, costs, interest and punitive damages.

COUNT III

Relator, Ebonia Elliott-Lewis, Against Abbott for Retaliation in Violation of U.S.C. Section 3730(h)

70. The Relator, Elliott-Lewis, repeats and restates the allegations contained in paragraphs 1 through 69 and incorporate said allegations herein by reference.

71. At all relevant times Elliott-Lewis was engaged in protected activity for raising concerns about the marketing and sales tactics used by Abbott, which he believed to be illegal and improper. In retaliation for his complaints, Abbott improperly terminated Elliott-Lewis on May 9, 2014.

WHEREFORE, the Relator, Elliott-Lewis, demands judgment against the defendant, in An amount that this Honorable Court shall deem just and proper, together with attorneys fees, costs, interest and punitive damages.

Respectfully Submitted,
The Plaintiff,
By Her Attorney,

/s David P. Angueira
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Dated: August 12, 2014

[1] Evidence 7.PDF (Regional Medical Science Manager job description)
[2] Abby Trainor2.PDF
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[19] Evidence 17.PDF (C. Baird Field ride conversation)
[20] Evidence 15.PDF
[21] Evidence 27.PDF
[22] Evidence 28.PDF
[23] 2013 Assessment Eboni_27Feb2013.PDF (Ebonia Elliott-Lewis 2013 Performance Assessment)
[24] Evidence 18.PDF
[25] Evidence 19.PDF
[26] Elliott-Lewis ERFILEREQ 8000744702.zip (Ebonia Elliott-Lewis Abbott full personnel history)
[27] Evidence 33.PDF (Performance praise from Krishna Sudhir)
[28] Evidence 32.PDF (Performance praise from Chuck Simonton)
[29] 2013 Review Rebuttal_FINAL COPY.PDF
[30] 2013 Performance Review Rebuttal meeting- EMAIL.PDF
[31] Krishna 2014 goals - AVSH MedSci.PDF (Krishna Sudhir 2014 Performance Metrics)
[32] TMS goals 4.JPEG - Ebonia Elliott-Lewis 2014 Performance Metrics
[33] Evidence 35.PDF
[34] AV Medical Science Manager BUS2072356 .PDF (AV MSM Manager Acceptable Practices Policy)
[35] VIVA Commercial Support.PDF
[36] VIVA 2013-RD.PDF (VIVA 2013 Regina Deible presentation slides)
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[40] MDT 1-month DAPT slide
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[54] OEC helpline response.PDF
[55] Pete S 1.PDF
[56] Dear Jim after review rebuttal meeting3.PDF
[57] Evidence 31.PDF
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